PATENT COOPERATION TREATY

Plougmann & Vingtoft

20 DEC. 2004

WJM/SW 14

From the
INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

To:

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PCT

NOTIFICATION OF TRANSMITTAL OF THE INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Rule 71.1)

Date of mailing *(day/month/year)*	17.12.2004
Applicant's or agent's file reference: 31505 PC 01	**IMPORTANT NOTIFICATION**

International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/DK 03/00605	18.09.2003	18.09.2002

Applicant
HVIDOVRE HOSPITAL et Al.

1. The applicant is hereby notified that this International Preliminary Examining Authority transmits herewith the international preliminary examination report and its annexes, if any, established on the international application.

2. A copy of the report and its annexes, if any, is being transmitted to the International Bureau for communication to all the elected Offices.

3. Where required by any of the elected Offices, the International Bureau will prepare an English translation of the report (but not of any annexes) and will transmit such translation to those Offices.

4. **REMINDER**

The applicant must enter the national phase before each elected Office by performing certain acts (filing translations and paying national fees) within 30 months from the priority date (or later in some Offices) (Article 39(1)) (see also the reminder sent by the International Bureau with Form PCT/IB/301).

Where a translation of the international application must be furnished to an elected Office, that translation must contain a translation of any annexes to the international preliminary examination report. It is the applicant's responsibility to prepare and furnish such translation directly to each elected Office concerned.

For further details on the applicable time limits and requirements of the elected Offices, see Volume II of the PCT Applicant's Guide.

The applicant's attention is drawn to Article 33(5), which provides that the criteria of novelty, inventive step and industrial applicability described in Article 33(2) to (4) merely serve the purposes of international preliminary examination and that "any Contracting State may apply additional or different criteria for the purposes of deciding whether, in that State, the claimed inventions is patentable or not" (see also Article 27(5)). Such additional criteria may relate, for example, to exemptions from patentability, requirements for enabling disclosure, clarity and support for the claims.

Name and mailing address of the international preliminary examining authority:	Authorized Officer
European Patent Office - P.B. 5818 Patentlaan 2 NL-2280 HV Rijswijk - Pays Bas Tel. +31 70 340 - 2040 Tx: 31 651 epo nl Fax: +31 70 340 - 3016	Rasmussen, S Tel. +31 70 340-4595

Form PCT/IPEA/416 (January 2004)

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference 31505 PC 01	**FOR FURTHER ACTION**	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)
International application No. PCT/DK 03/00605	International filing date *(day/month/year)* 18.09.2003	Priority date *(day/month/year)* 18.09.2002
International Patent Classification (IPC) or both national classification and IPC A61M16/08		
Applicant HVIDOVRE HOSPITAL et Al.		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 4 sheets, including this cover sheet.

   ☒ This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

   These annexes consist of a total of 3 sheets.

3. This report contains indications relating to the following items:

   - I ☒ Basis of the opinion
   - II ☐ Priority
   - III ☒ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
   - IV ☐ Lack of unity of invention
   - V ☒ Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
   - VI ☐ Certain documents cited
   - VII ☐ Certain defects in the international application
   - VIII ☐ Certain observations on the international application

Date of submission of the demand	Date of completion of this report
14.04.2004	17.12.2004
Name and mailing address of the international preliminary examining authority: European Patent Office - P.B. 5818 Patentlaan 2 NL-2280 HV Rijswijk - Pays Bas Tel. +31 70 340 - 2040 Tx: 31 651 epo nl Fax: +31 70 340 - 3016	Authorized Officer Villeneuve, J-M Telephone No. +31 70 340-2893

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No. PCT/DK 03/00605

I. Basis of the report

1. With regard to the **elements** of the international application *(Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17))*:

Description, Pages

1-12	as originally filed

Claims, Numbers

6, 9-22	as originally filed
2, 3	received on 28.09.2004 with letter of 28.09.2004
1, 4, 5, 7, 8	received on 07.12.2004 with letter of 07.12.2004

Drawings, Sheets

1/4-4/4	as originally filed

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

   These elements were available or furnished to this Authority in the following language: , which is:

   ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).

   ☐ the language of publication of the international application (under Rule 48.3(b)).

   ☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

   ☐ contained in the international application in written form.

   ☐ filed together with the international application in computer readable form.

   ☐ furnished subsequently to this Authority in written form.

   ☐ furnished subsequently to this Authority in computer readable form.

   ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.

   ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

   ☐ the description, pages:

   ☐ the claims, Nos.:

   ☐ the drawings, sheets:

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)).

   (Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)

6. Additional observations, if necessary:

III. Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

1. The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non-obvious), or to be industrially applicable have not been examined in respect of:

   ☐ the entire international application,

   ☒ claims Nos. 21, 22

   because:

   ☐ the said international application, or the said claims Nos. relate to the following subject matter which does not require an international preliminary examination (specify):

   ☐ the description, claims or drawings *(indicate particular elements below)* or said claims Nos. are so unclear that no meaningful opinion could be formed *(specify)*:

   ☐ the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed.

   ☒ no international search report has been established for the said claims Nos. 21, 22

2. A meaningful international preliminary examination cannot be carried out due to the failure of the nucleotide and/or amino acid sequence listing to comply with the standard provided for in Annex C of the Administrative Instructions:

   ☐ the written form has not been furnished or does not comply with the Standard.

   ☐ the computer readable form has not been furnished or does not comply with the Standard.

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes:	Claims	1-20
	No:	Claims	
Inventive step (IS)	Yes:	Claims	1-20
	No:	Claims	
Industrial applicability (IA)	Yes:	Claims	1-20
	No:	Claims	

2. Citations and explanations

see separate sheet

Re Item III

Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

No examination was carried out for claims 21, 22 because the subject matter of these claims is a method for treatment of the human or animal body by therapy (Article 34 (4)(a)(I) and Rule 67 (iv) PCT)

Re Item V

Reasoned statement with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1 Reference is made to the following document:
D1: WO 01/76658 A (DEROYAL IND INC) 18 October 2001 (2001-10-18)

1.1 The document Do is regarded as being the closest prior art to the subject-matter of claim 1.
This document discloses an adjustable pressure reducing valve. The subject matter of claim 1 is therefore new (Article 33 (2) PCT).

1.2 The pressure reducing valve of claim 1 differs from Do in that it is non adjustable. The problem to be solved by the present invention may therefore be regarded as excluding the possibility of an accidental misadjustment of the valve.
The solution proposed in claim 1 is not disclosed or suggested by the available prior art. Claim 1 is thus considered inventive in the sense of Article 33 (3) PCT.

1.3 Claims 2-20 meet the criteria of Article 33 (1) PCT because they are dependent on claim 1.

New claims of 7 December 2004

1. A non-adjustable pressure reducing valve for nasal supplying of a flow of air to a patient, said valve comprising;

- a hollowed tubular member defining an internal continuous flow passage extending from a high pressure air inlet end part, adapted to receive a flow of air from an air supplying conduit, to a low pressure air outlet end part opposite to said inlet end part and adapted to be connected to respiratory means for delivering a first part of said flow of air to the patient, and an intermediate air venting part having perforation(s) for venting a second part of said flow of air from said flow passage of the tubular member into the ambient atmosphere, and

- a shielding member being attached to the tubular member such that a space is defined between an outer surface of the air venting part and an inner surface of the shielding member in order to provide a shield above said perforation(s), said space being closed at the end towards the air outlet end part and open at the opposite end towards the air inlet end for directing the second part of the air flow from said perforations towards said air inlet end part.

2. A valve according to claim 1, wherein the air inlet part, the air outlet part and the intermediate air venting part form an integrated unit.

3. A valve according to claim 1 or 2, wherein the valve is made in one piece.

4. A valve according to claim 1 or 2, wherein the shielding member comprises a capsule-like member to be attached to the tubular member, the capsule having an internal peripheral portion with a flange section for shielding said perforation(s) and an attachment section for attaching it to the tubular member, the radial size of the flange section being larger than the radial size of the part of the tubular member comprising the perforation(s) whereas the radial size of the attaching section being equal to or smaller than the radial size of a part of the tubular member located between the perforation(s) and the air outlet.

5. A valve according to any of claims 1, 2 and 4, wherein the tubular member comprises an external peripheral portion between the high pressure air inlet end part and the low pressure air outlet, said external peripheral portion comprising a stepped configuration or a flange for receiving and holding said attachment section of the shielding member.

6. A valve according to any of claims 1-5, wherein the shielding member is a tubular body of revolution surrounding the air venting part.

7. A valve according to any of claims 1, 2 and 4-6, wherein the shielding member is a separate part attached to the tubular member.

8. A valve according to any of claims 1, 2 and 4-7, wherein the shielding member is fixed attached to the tubular member.

9. A valve according to any of claims 3-8, wherein the distance between said outer surface of the air venting part and said inner surface of the shielding member is between 0.5-5 mm, such as 1 or 2 mm.

10. A valve according to any of the preceding claims, wherein the diameter of the inlet end part is 4-8 mm, such as 6 mm.

11. A valve according to any of the preceding claims, wherein the diameter of the outlet end part is 2-5 mm, such as 3 mm.

12. A valve according to any of the preceding claims, wherein the perforations comprise four air passages substantially even distributed around the circumference of the tubular member.

13. A valve according to claim 12, wherein the angle between the centre lines of the air passages is substantially 90°.

14. A valve according to claim 13, wherein the diameter of the one pair of oppositely arranged air passages is different from the diameter of the other pair of oppositely arranged air passages.

15. A valve according to any of the preceding claims, wherein the diameter of the perforation(s) is between 1-10 mm, such as 2-9 mm, such as 3-8 mm, such as 4-7 mm, such as 5-6 mm.

16. A valve according to any of the preceding claims, wherein the valve is disposable.

17. A valve according to any of the preceding claims, wherein the inner cavity and the perforation(s) of the air venting part are shaped and dimensioned so as to reduce an air inlet overpressure of 6-7 bars to an air outlet overpressure of 2-7 cm water column.

18. A valve according to any of the preceding claims, wherein the air venting part is adapted to vent 50% or more of the air flowing through the inner cavity of the valve into the ambient atmosphere.

19. A valve according to any of the preceding claims, wherein the low pressure air outlet comprise a flange for connecting a nasal prong section thereto.

20. A valve according to any of the preceding claims, wherein the low pressure air outlet is constituted by a nasal prong section having first and second nasal prong air outlets.

21. A method of providing gas to a CPAP (Continuous Positive Airway Pressure) valve, said method comprising conveying gas under a first pressure from a gas supply to at least two gas passages, one passage extending towards an outlet in a direction towards a patient and the other passage extending towards an outlet in an opposite direction so as to reduce the pressure of the air coming out of the outlet to a pressure level below said first pressure.

22. A method of providing gas to a CPAP (Continuous Positive Airway Pressure) valve, said method comprising conveying gas under a first pressure from a gas supply through a valve according to any of claims 1-20.